

REMARKS

This paper is filed in response to the Office action mailed on January 6, 2006. Claims 1-40, 52-55, 57-58, 64-67, 69-70, and 76-77 were previously presented in the application. Of these, claims 2-16, 18, 23-38, 40, 53-55, 58, 65-67, 70, and 76-77 have been withdrawn from consideration. Claims 1, 18, 20, 35, 40, 52, 58, 64, and 70 are amended herewith. All pending claims stand rejected and are at issue in the present application. In view of the amendments and remarks presented herein, reconsideration and allowance of all pending claims are respectfully requested.

The Office action rejects claims 1, 17, 20, 22, 39, 64, and 69 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,102,890 ("Stivland"). Applicants respectfully traverse this rejection.

Independent claims 1, 20, and 64 as amended recite a hypotube having a tubular shaft with a main section connected to a distal section. The distal section includes a first section connected to a second section, wherein the first section is disposed between the main section and the second section. The first section includes at least one slit extending through the tubular wall and at least partially and circumferentially around the tubular wall. A non-tubular stinger is formed in or attached to the second section. Support for the stinger being non-tubular is found in the specification at page 6, lines 3-6 and lines 23-25, which describe the stinger as being an extension of a portion of the hypotube, and in Figs. 1-10 and 14-17 as originally submitted with the application, which illustrate non-tubular stingers. It is not seen that Stivland discloses or suggests such a structure.

Instead, Stivland discloses catheters having hypotube distal portions that are tubular. Specifically, each embodiment disclosed in Stivland includes a distal end wall structure that forms a conduit, and therefore is constantly tubular. Consequently, Stivland fails to disclose at least the non-tubular stinger specified in claims 1, 20, and 64, and therefore the anticipation rejection of these claims must be withdrawn.

The Office action also rejects claims 19, 21, 52, and 57 under 35 U.S.C. § 103(a) as being obvious over Stivland in view of U.S. Patent No. 6,575,958 ("Happ"). Applicants respectfully traverse this ground of rejection.

Independent claim 52, as well as claim 57 dependent directly thereon, specifies a hypotube including, *inter alia*, a tubular shaft having a tubular wall with a distal section. The distal section includes at least one slit extending through the tubular wall and at least partially and circumferentially around the tubular wall. The distal section further includes an elongated cut-out along the tubular wall that forms a non-tubular stinger. The at least one slit is disposed in close proximity to the stinger. Thus, the claim recites a combination of at least two different flexibility enhancing elements incorporated into a hypotube, namely a tubular slotted portion and a non-tubular stinger portion. The cited prior art fails to disclose or suggest the claimed hypotube.

As noted above, Stivland fails to expressly teach a hypotube having a non-tubular stinger portion. Stivland also fails to disclose or suggest a hypotube distal end having at least two different flexibility enhancing elements, namely the combination of a tubular slotted portion and a non-tubular stinger portion.

Happ fails to provide the deficiencies noted with respect to Stivland. Specifically, Happ teaches the use of a combination of separate components to improve flexibility characteristics of a catheter. Specifically, Happ discloses a transition section 118 of the catheter that includes at least a distal end 115 of a hypotube and a separate tubular support member 130. The tubular support member 130 is attached between the proximal and distal shafts of the catheter and is placed around the distal end of the hypotube. It includes a composite tubular member 148, which preferably includes a tubular metallic member 151, which may be a layer of metallic strand 154, sandwiched between inner and outer layers 160, 163 of high strength polymeric materials. (Col. 5, line 49 to Col. 6, line 4). Accordingly, Happ teaches a combination of components, including at least the distal tip 115 of the hypotube and the composite, multi-layered tubular member 130, to improve flexibility and kink-resistance of the catheter. Consequently, the combination of Stivland and Happ fail to disclose or suggest a hypotube having a slotted portion and a non-tubular stinger portion as claimed, and therefore the obviousness rejection must be withdrawn.

Furthermore, there is no motivation to combine Stivland and Happ in the manner suggested by the Examiner. The mere fact that references *can* be modified is *not* sufficient to establish a *prima facie* case of obviousness “unless the prior art also suggests the desirability of the combination.” *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990)”

(emphasis original). In order to establish a *prima facie* case of obviousness, there must be *actual evidence* of a suggestion to modify a prior art reference or to combine two prior art references, and the suggestion to combine or modify the prior art must be clear *and particular*. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). It is improper to use hindsight to combine the prior art references, as noted in *Orthopedic Equipment Co. v. United States*, 217 U.S.P.Q. 193, 199 (Fed. Cir. 1983), which noted that “It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.” The Federal Circuit has observed that the use of hindsight can be a trap for the unwary, noting:

Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one ‘to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.’ Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.
In re Dembiczak, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 2000)(citations omitted)(emphasis added)

The proper inquiry when determining nonobviousness is whether “there is something in the prior art as a whole *to suggest* the desirability, and thus the obviousness, of making the combination.” *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556, 225 U.S.P.Q. 26, 31 (Fed. Cir. 1985) (emphasis in original). With the foregoing as guidance, it is clear that the proposed combination of Stivland and Happ is improper.

First, the Examiner incorrectly states that Happ teaches the use of a cut-out to improve flexibility kink resistance of a catheter. Happ instead teaches the use of multiple separate components to achieve the desired characteristics, namely the transition section 118 having at least the distal tip 115 of the hypotube and a tubular support member 130 as noted

above. Accordingly, it is incorrect to assert that Happ simply teaches the use of a cut-out to improve flexibility when in fact it teaches a combination of components to achieve this.

In the most recent Office action, the Examiner responds to applicant's position regarding lack of motivation to combine by listing several observations purportedly supported by the Happ disclosure. These statements either do not directly support the Examiner's contention that Happ specifically teaches the use of a cut-out to improve kink resistance or incorrectly characterize what is disclosed in Happ in an attempt to improperly bolster the Examiner's position. For example, the Examiner refers to column 5, lines 40-43, of Happ in support of this position. This portion of Happ, however, states that the tubular support member 130 provides the transition 118 with greater flexibility than the more rigid proximal shaft section 16, and therefore supports applicant's position that Happ teaches the use of a combination of elements, including the tubular support member 130, rather than the cut-out alone, to improve flexibility and stiffness of the catheter.

Similarly, the Examiner's citation to column 2, lines 43-45 of Happ supports the Applicant's position. This portion of Happ states, "The present invention includes various embodiments for minimizing the bending stiffness differential as well as increasing the overall flexibility of the catheter." The excerpt from Happ cited by the Examiner does not tie the objectives of overall flexibility and minimizing bending stiffness differential to the "lengths and placement of components," and therefore the Examiner improperly characterizes what is taught in Happ. It is also instructive to note that each of the various embodiments disclosed by Happ, as well as the claims, also includes a tubular support member, and therefore it is not seen that Happ discloses or suggests a modification to the hypotube alone to achieve the desired characteristics. Consequently, no valid motivation exists to combine Happ and Stivland as proposed by the Examiner to arrive at the claimed subject matter, and therefore the rejection based thereon must be withdrawn.

The proposed combination is also improper since it would render the Stivland device unsatisfactory for its intended purpose. It is well settled that there is no motivation or suggestion to combine where a proposed modification renders a device inadequate for its intended purpose. MPEP Section 2143.01 states:

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then

there is no suggestion or motivation to make the proposed modification. Citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In the present application, the Examiner proposes to modify Stivland, which teaches a spiral cut formed across the entire distal end of the hypotube resulting in a continuous, spiral shaped, tubular distal end, with Happ, which discloses a tapered hypotube tip formed by removing a portion of the hypotube. If the spiral distal end of Stivland is tapered by removing a portion of the hypotube, as taught in Happ, the spiral cut will separate the distal tip into multiple, unconnected tip pieces, resulting in a lack of continuity between the multiple tip pieces and therefore exacerbating the problem of kinking in this area of the catheter. Accordingly, the proposed combination of references is improper and the rejection based thereon must be withdrawn.

The most recent Office action appears to improperly challenge the well-settled rule finding no motivation or suggestion exists for modifications that render the prior art device inadequate for its intended use. Specifically, the Examiner replies to applicant's position by stating:

In response to applicant's argument that the proposed combination would render the Stivland device unsatisfactory for its intended use, the test for obviousness is not whether the features of the secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art...In this case, the elongated cut-out in the axial direction along the tubular wall of Happ et al may be bodily incorporated into the distal end tip of the hypotube [sic] of Stivland et al..."

To the extent the Examiner intended to reject the statement of law offered by the applicant, he is incorrect, as noted above. Furthermore, this excerpt from the Office action mischaracterizes applicant's previous arguments and presents contradictory statements regarding the standards for determining motivation to combine references.

First, at no point has applicant simply argued that features of Happ are not capable of being "bodily incorporated" into Stivland. Instead, applicant's position assumes that the cut-

out of Happ can be bodily incorporated into the spiral cut of Stivland, and instead focuses on the result of such a proposed combination.

In addition, the Examiner concludes with an observation regarding the proposed combination that is completely unrelated to the issue of motivation to combine and appears to contradict the Examiner's statements made earlier in the same paragraph. Specifically, the Examiner concludes by observing that the cut-out of Happ "may be bodily incorporated into the distal end tip of the hyptotube [sic] of Stivland et al." As noted earlier in the same paragraph of the Office action, however, the Examiner argued that the test of obviousness "is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference..." It would appear that the Examiner is suggesting that the ability to "bodily incorporate" the two references somehow positively supports his conclusion that motivation to combine exists. Accordingly, it is not seen how the Examiner's observation regarding the ability "bodily incorporate" Stivland and Happ are relevant to the obviousness issue. Even if the cut-out of Happ is capable of being incorporated into the Stivland structure, such a combination would render Stivland inadequate for its intended use as noted above, and therefore no motivation exists to combine the references. The obviousness rejection based on the proposed combination of Stivland and Happ must therefore be withdrawn.

Claim 57 depends from claim 52, and therefore is patentable over the cited prior art for the same reasons presented above. Furthermore, independent claims 1, 20, and 64, as well as the claims depending therefrom, recite the same elements noted above with respect to claim 52, and therefore these claims are also patentable over the combination of Stivland and Happ.

Applicant further requests rejoinder of the claims previously withdrawn in response to the election of species requirement. The Office previously asserted both a restriction requirement between the apparatus and method claims originally presented and an election of species requirement. All of the withdrawn method claims have been canceled. Certain of the remaining apparatus claims were withdrawn in view of the election of species requirement. Each of these claims, however, depends from one of independent claims 1, 20, 52, and 64, which Applicant submits are now in condition for allowance. Accordingly, each of the remaining withdrawn claims recites each of the elements of an allowable claim, and therefore

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is eligible for rejoinder. Reconsideration and withdrawal of the election of species requirement are therefore respectfully requested.

CONCLUSION

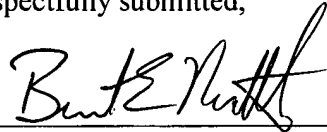
It is submitted that the present application is in good and proper form for allowance. A favorable action on the part of the Examiner is respectfully solicited.

If, in the opinion of the Examiner a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

The Commissioner is authorized to charge any fee deficiency required by this paper, or credit any overpayment, to Deposit Account No. 50-3629.

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Respectfully submitted,

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